

## AMENDMENT AND RESPONSE TO OFFICE ACTION

Docket No. 15872.091

Title: "Bioactive Compounds Protection Method and Compositions Containing the Same"

U.S. Serial No. 10/561,541

REMARKS

Claims 106 and 107 have been amended, claims 1-87, 97, 100, and 102 have been cancelled, and new claims 116-120 are added herein. Thus, claims 88-96, 98-99, 101, 103-107, and 108-120 are presently pending, of which claims 88-96, 98-99, 101, 103-105, and 108-115 have been withdrawn from consideration and claims 106-107 and 116-120 are currently being examined. The following changes have been made pursuant to the Examiner's request: claim 106 has been rewritten as an independent claim, and claim 107 has been amended to properly depend from 106. Claim 106 has been further amended to explicitly include the limitations set forth in claims 88 and 101, which were previously incorporated by reference. No new matter has been added, because, as explained above, support for each new or amended claim comes directly from previously filed claims. Entry of the amendments at this time is therefore respectfully requested.

Before referring to the cited patents and addressing the rejections raised by the Examiner, it is to be noted that currently pending claim 106 is drawn to a method for improving the health status of a mammal (emphasis added). New Claims 116-120 are dependent on claim 106, directly or indirectly.

The Examiner rejects claims 106-107 as being unpatentable over Anderson (U.S. Patent No. 6,482,517) and Mandralis et al. (U.S. Patent No. 6,048,562).

Anderson teaches a method of making a coated particle in liquid phases of active compound and the encapsulated material. Mandralis et al. teach an encapsulating process by mixing a core material with an aqueous medium comprising a natural food polymer as an encapsulant, aimed at overcoming the need to employ denaturation at very high temperatures (100-180°C) and cross-linking. Applicant respectfully submits that the coated particles of Anderson and the methods for making them are significantly different from those of the present invention. The solution provided by Mandralis et al. to avoid the denaturation and cross-linking is to use high pressure and a temperature up to 100°C, none of which are used, or suitable to be used, according to the teachings of the present invention. The presently claimed method specifically requires administration of heat-sensitive bioactive ingredients to improve the health

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of the subject, wherein the bioactive ingredient must be encapsulated in a particular way to ensure the intended benefit. This aspect is critical to the overall benefit provided by the presently claimed method of improving the health a mammal. Anderson and Mandralis et al. do not teach this method.

As acknowledged by the Examiner, neither of the cited references explicitly teaches adding the encapsulating material to a food, feed or drink. The Examiner states that Anderson teaches that encapsulating vegetable fats in cattle feeds is a conventional practice in the art and that one of ordinary skill in the art would be motivated to incorporate the encapsulated nutrients of Anderson et al., and Mandralis et al. to food, feed or drink to stabilize the material and increase shelf life. It is to be noted, however, that nowhere in Anderson and/or Mandralis et al., is a method for improving the health status of a mammal disclosed or even suggested, and especially not the presently claimed method. Thus, there is no support for this argument.

In addition, Anderson and/or Mandralis et al. certainly do not teach or suggest a method of improving the health of a mammal by administering to the mammal a newborn edible food or feed formulation having a heat sensitive bioactive ingredient encapsulated by:

- (i) mixing the heat sensitive bioactive ingredient with an encapsulating material, wherein said encapsulating material is food-grade or feed-grade materials, either alone or in combination, with a liquid, forming a liquid blend;
- (ii) drying the liquid blend forming a dry blend;
- (iii) coating the dry blend with at least one additional encapsulating layer;
- (iv) mixing the dry blend with at least one additional food-grade or feed-grade material; and
- (v) adding the dry blend to the mammalian newborn formulation, wherein the steps of admixing all of the ingredients and drying are conducted at a temperature below 50°C, such that the activity of the heat sensitive bioactive ingredient is substantially maintained.

The presently claimed method provides benefits not demonstrated in the cited prior art. For example, the weight gain and health improvement in bovine and caprine neonates fed

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according to the claimed method, using the heat-sensitive bioactive ingredient, particularly insulin, encapsulated as claimed (Examples 1-2, paragraphs [0136]-[0143] of the instant specification). To Applicant's knowledge, this is the first time that heat-sensitive bioactive proteins, administered orally, maintained their activity and exerted their effects to cause weight gain and further improve the health of a mammal. Thus, it was surprising and unexpected.

Accordingly, Applicant respectfully submits that the presently claimed method taught by Applicant herein, for improving the health status of a mammal by administering a food or feed formula comprising heat sensitive bioactive ingredient encapsulated by the particularly claimed method is novel and inventive, as the cited prior art fails to teach the elements as claimed.

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding objections and rejections and pass this application to issue. If there are any questions, the Examiner is invited to call Applicant's representative Rodney Fuller at (602) 916-5404 to resolve any remaining issues to expedite the allowance of this application.

Respectfully submitted,

November 20, 2009

Date

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